REMARKS

Reconsideration And Allowance Are Respectfully Requested.

Claims 1-7, 16, 17, 22-24, 31, 33, 34 and 111-121 are currently pending. Claims 1, 22, 23, 24, 31, 33 and 111 have been amended. Claims 112-121 have been withdrawn from consideration. Claims 8-15, 18-21, 25-30, 32 and 35-110 were canceled by way of a previous amendment. No new claims have been added. No new matter has been added. Reconsideration is respectfully requested.

Claims 1-7, 16, 17, 22-24, 31, 33, 34 and 111 are objected to because of informalities. These informalities have been addressed and Applicants respectfully request the objections relating thereto be withdrawn. With regard to claim 1, it was clear and has been made clearer that the bodies are made from different materials. With regard to claim 111, one of the at least two implantable bodies being made from an expandable material is a further structural limitation.

Claims 1-7, 16, 17, 22-24, 31, 33, 34 and 111 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claim 1 has been amended to remove "ultrasonically", and inserted "via non-invasive techniques". Support for this amendment is found in paragraph [0057] of the present application. Thus, this rejection is deemed to have been overcome and Applicants respectfully request that it be withdrawn.

Claims 1-7, 16, 17, 22-24, 31, 33, 34 and 111 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been amended in an effort to overcome the rejection and claims 1-7, 16, 17, 22-24, 31, 33, 34 and 111 are now believed to fully

comply with 35 U.S.C. § 112, second paragraph. As such, Applicants respectfully request these rejections be withdrawn.

With regard to the rejections based upon references cited in the Office Action, claims 1-7, 16, 22, 23, 24, 31, 33, 34 and 111 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0012652 to Levy et al. ("Levy") in view of U.S. Patent No. 6,106,473 to Violante et al. ("Violante") and U.S. Patent No. 6,197,324 to Crittenden ("Crittenden") and U.S. Patent No. 5,632,775 to Suding et al. ("Suding") or U.S. Patent No. 4,985,019 to Michelson ("Michelson"). Claim 17 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy in view of Violante and Crittenden and Suding or Michelson, and further in view of U.S. Patent No. 6,666,811 to Good ("Good"). These rejections are respectfully traversed in view of the preceding amendments and the remarks which follow.

To begin with, the claims of the present application all claim a subcutaneous cavity marking device. Not one of the cited references is directed to a subcutaneous marking device. It is not clear how the combination of cited references, not one of which discloses a critical limitation of the claimed invention, can render something they fail to teach to be obvious.

The base reference of Levy teaches microspheres containing condensed polyanionic bioactive agents and a method for their production. Regardless of how Levy is modified, the end result is not a subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure. To quote Levy in paragraph [0055], "The present invention is useful for preparations of a wide variety of polyanionic bioactive agents. The agents described infra primarily exert their bioactive effect by causing direct changes to the cell. However, the term "bioactive" as

used in this Application is intended to include any substance that interacts with biological elements. Thus, bioactive agents include substances such as dyes or labeling proteins whose primary use is to facilitate identification or visualization of biological structures or functions".

A microsphere containing a bioactive agent which effects and causes direct changes to cells such that they can be identified or visualized is certainly not a subcutaneous marking device that would be used during any type of biopsy. No one in the medical field would intentionally use a microsphere containing a bioactive agent during a biopsy to mark a site. It is well established that a marker used during a biopsy should not affect the surrounding tissue and thus something containing a bioactive substance as disclosed by Levy would not, and could not, effectively be used as a subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure.

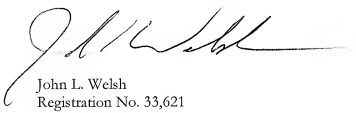
Whether to treat a preamble as a limitation is a determination "resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Id.; Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). In general, a preamble limits the claimed invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. Catalina Mktg., 289 F.3d at 808, 62 USPQ2d at 1784 (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)).

Both the specification and prosecution history of the present application make clear that the phrase "subcutaneous cavity marking device" defines the claimed invention and is, therefore, a limitation of the claims. The preamble recites "A subcutaneous cavity marking device

percutaneously implantable in breast tissue during a biopsy procedure" and the pertinent case law holds that the preamble is given weight if it breathes life and meaning into the claim. Surely in this case the preamble breathes life and meaning into the claim. Accordingly, the cited prior art does not anticipate or render obvious the claims because not a single cited reference teaches a subcutaneous cavity marking device percutaneously implantable in breast tissue during a biopsy procedure.

It is believed that this case is in condition for allowance and reconsideration thereof and early issuance is respectfully requested. If it is felt that an interview would expedite prosecution of this application, please do not hesitate to contact Applicants' representative at the below number.

Respectfully submitted,



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